III. 510(K) SUMMARY

AUG 3 2012

LifeCell Corporation's LTM-Laparoscopic Surgical Mesh

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876

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Date Prepared: April 27, 2012

Name of Device and Name and Address of Sponsor

LTM-Laparoscopic Surgical Mesh
LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876

Common or Usual Name

Surgical Mesh

Classification Name

Surgical Mesh

Classification

Class II

Product Code

FTM

Predicate Devices

LTM Surgical Mesh (K070560) – LifeCell Corporation

Reference Devices
Restorelle Polypropolene Mesh (K103568) – C.R. Bard
Surgimesh XD (K092233) - Aspide Medical
Surgimesh WN (K061445) - Aspide Medical

Intended Use / Indications for Use
LTM-Laparoscopic Surgical Mesh is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome during open or laparoscopic procedures.

LTM-Laparoscopic Surgical Mesh is intended for single patient one-time use only.

Technological Characteristics
The LTM-Laparoscopic Surgical Mesh is a surgical mesh that is derived from porcine dermal tissue. The LTM-Laparoscopic Surgical Mesh device consists of a terminally sterilized sheet of the processed porcine dermal matrix provided in prescribed geometric configurations and sizes ranging from 10 cm x 16 cm to 20 cm x 20 cm, with future sizes planned ranging from 2 cm x 2 cm to 20 cm x 30 cm. It will be packaged in double pouch configuration.

Performance Data
LTM-Laparoscopic Surgical Mesh is within the existing specification window and is manufactured with, the same process as LTM Surgical Mesh (K070560) (*e.g.,* material source, processing methods to ensure purity, and packaging). LTM Surgical Mesh (K070560) has undergone extensive biocompatibility testing, animal testing, viral inactivation testing, and biomechanical testing. The data indicates that the device is biocompatible and that the manufacturing process is capable of inactivating any viral components that may come with the starting material. The LTM-Laparoscopic Surgical Mesh went through the same biomechanical testing after laparoscopic handling (**Attachment 1**) and possesses sufficient strength and suture retention for the intended use. This fully supports use during open or laparoscopic procedures.

Substantial Equivalence
LTM-Laparoscopic Surgical Mesh is substantially equivalent to the legally marketed predicate device, LifeCell Corporation's LTM Surgical Mesh (K070560), which has been cleared by the FDA for use as a surgical mesh to be implanted to reinforce soft tissue where weakness exists in abdominal wall procedures.

LTM-Laparoscopic Surgical Mesh is technologically similar to LifeCell's recently cleared LTM Surgical Mesh (K070560). The laparoscopic conditioning data (**Attachment 1**) show that LTM-Laparoscopic Surgical Mesh meets Tensile Strength, Tear Resistance, Suture Pull-out Strength, and Burst Strength specifications as

established for the predicate device (K070560). The laparoscopic conditioning of LTM-Laparoscopic Surgical Mesh (rolling, introduction into abdomen, and grasper interface) is consistent with the handling of the reference laparoscopic surgical meshes (i.e. Restorelle Polypropolene Mesh (K103568), Surgimesh XD (K092233), and Surgimesh WN (K061445), which have all been cleared for the laparoscopic use indication). LTM-Laparoscopic Surgical Mesh maintains its biomechanical integrity before and after laparoscopic conditioning making it substantially equivalent for open or laparoscopic procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 3 2012

Lifecell Corporation
% Mr. Mark R. Jakubowski
1 Millenium Way
Branchburg, New Jersey 08876

Re: K121289
Trade/Device Name: LTM-Laparoscopic Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OXK
Dated: June 27, 2012
Received: June 28, 2012

Dear Mr. Jakubowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Indications For Use Statement

510(K) Number (if known):

Device Name: LTM-Laparoscopic Surgical Mesh

Indication for Use:

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Prescription Use (21 CFR Part 801 Subpart D)	**XX**	AND/OR	Over the Counter Use ___ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

____Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121269